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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,310

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Jorgen Carlsson

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03/24/2010

WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

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MAIL DATE

DELIVERY MODE

03/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,310	Applicant(s) CARLSSON ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-33, 35-41, 47, 49, 52-54, 56, 58 and 59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-33, 35-41, 47, 49, 52-54, 56, 58 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. **THE FINALITY OF THE LAST OFFICE ACTION IS HEREBY VACATED.**
2. Applicants' Response to Advisory Action, received 4 February 2010, is acknowledged. Claims 1, 21, 28, 29 and 33 have been amended. Claims 34 and 55 have been cancelled.
3. Claims 1-3, 5-33, 35-41, 47, 49, 52-54, 56, 58 and 59 are pending and under consideration.

Rejections/Objections Moot or Withdrawn

4. The rejection of claim 33 under 35 U.S.C. 112, second paragraph, as being indefinite for "corresponds to", is withdrawn in light of the amendment of the claim.
5. The rejection of claim 55 under 35 U.S.C. 112, second paragraph, as being indefinite for "positive" and "negative" slides, is moot in light of the cancellation of the claim.
6. The objection to claims 28 and 29 under 37 CFR 1.75(c) as being in improper form, is withdrawn in light of the amendment of the claims.
7. The rejection of claims 1-3, 5-33, 35-41, 47, 49, 52-54, 56, 58 and 59 under 35 U.S.C. 112, second paragraph, as being indefinite for "derive", is withdrawn in light of the amendment of the claims.
8. The rejection of claims 34 and 55 under 35 U.S.C. 112, second paragraph, as being indefinite for "derive", is moot in light of the cancellation of the claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1645

10. Claims 1-3 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Uhlen et al (*J. Biol. Chem.*, 259(3):1695-1702, 1984).

Claim 1 is drawn to a polypeptide whose sequence comprises SEQ ID NO:1, having from 1 to about 20 substitution mutations thereon. Claim 25 is the polypeptide of claim 1, which comprises additional amino acid residues at either terminal.

Uhlen et al teach a polypeptide whose sequence comprises SEQ ID NO:1 having 2 substitutions thereon (Figure 3, residues 176-233 with substitutions at residues 176 and 203), with additional amino acid residues at both terminals.

Claims 2 and 3 are the structure of claim 1, which has a binding certain binding affinity to HER2. Since the Patent Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *in re Best*, 562 F.2D 1252, 195 USPQ 430 (CCPA 1977), and *in re Fitzgerald et al.*, 205 USPQ 594.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 5-24, 26-33, 35-41, 47, 49, 52-54, 56, 58 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from rejected claims.

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Conclusion

12. Claims 1-3, 5-33, 35-41, 47, 49, 52-54, 56, 58 and 59 are rejected.
13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 24, 2010